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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP 03/07859	International filing date *(day/month/year)* 18.07.2003	Priority date *(day/month/year)* 05.08.2002
International Patent Classification (IPC) or both national classification and IPC A61M5/20		
Applicant CARETEK MEDICAL LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 9 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☒ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
27.02.2004	15.11.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Ehrsam, F Telephone No. +49 89 2399-2343

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/07859

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-28 as originally filed

Claims, Numbers

1-57 filed with telefax on 02.10.2004

Drawings, Sheets

1/4-4/4 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

   see separate sheet

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 57

   because:

   ☒ the said international application, or the said claims Nos. 57 relate to the following subject matter which does not require an international preliminary examination (specify):

   see separate sheet

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees, the applicant has:

   ☐ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☒ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   ☐ complied with.

   ☐ not complied with for the following reasons:

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-37 .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	2-34,36
	No:	Claims	1,35,37
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-37
Industrial applicability (IA)	Yes:	Claims	1-37
	No:	Claims	

2. Citations and explanations

see separate sheet

The following documents are referred to in this communication; the numbering will be adhered to in the rest of the procedure:

D1: US-A-2 398 544 (LOCKHART) 16 April 1946 (1946-04-16)
D2: DE 38 39 287 A (HOLZER) 23 May 1990 (1990-05-23)
D3: US-A-4 871 094 (CLEMENTS ET AL.) 3 October 1989 (1989-10-03)
D4: US-A-4 518 387 (MURPHY ET AL.) 21 May 1985 (1985-05-21)
D5: FR-A-2 749 764 (MOREAU DEFARGES) 19 December 1997 (1997-12-19)
D6: US-A-5 542 920 (CHERIF CHEIKH ROLAND) 6 August 1996 (1996-08-06)
D7: US-B-6 203 5211 (MENNE ET AL.) 20 March 2001 (2001-03-20)
D8: EP-A-0 879 609 (AVANT DRUG DELIVERY SYSTEMS INC.) 25 November 1998 (1998-11-25)

See point I:

1. The Applicant has added the following feature to claims 1, 35 and 36:

   a) wherein said generating means (14) and said force transmitting means (20) are configured to push the drug (16) from the packaging (18) into the human or animal body at a velocity less than 20 m/s.

   The scope of this claim has therefore been extended. No basis for such an extension can be found in the application as filed and hence the claim as amended results in the application being amended in such a way that it contains subject-matter which extends beyond the content of the application as filed, contrary to Article 34 2) b) PCT.
   Indeed, the support mentioned by the applicant, in particular claim 5, specifies only that the drug is pushed from the packaging at a speed less than 10 m/s and not 20 m/s and not into the human or animal body as presently claimed.
   Furthermore, the velocity (less than 100 m/s) mentioned on page 4, lines 4-5 applies only for their earlier described invention and cannot be part of the present invention application. Moreover, the velocity less than 20 m/s disclosed on page 12, lines 1-2 concerns only the velocity of the impact of the hammer and no mention is further made of the velocity of the drug.
   To avoid such an objection, the added matter could have been replaced by original claim 5.

See point III:

1. The method claim 57 is not allowable since it is considered to define a surgical method and as such the subject-matter is not allowable Art. 34.4) a) i). Indeed, the claims comprise method steps which are in relation with the human body (see for instance the step of "administering through the skin" and inevitably a hole is cut in the patient to be able to introduce the needle.
The claims therefore do not conform with the requirements of article 34.4) a) i) PCT.

See point IV:

1. Furthermore, the application lacks unity within the meaning of Rule 13.1. The separate inventions or groups of inventions claimed in the application are the following:

A. Claims: 1-37

A drug delivery device

B. Claims: 38-56

A package drug

The present application lacks unity within the meaning of Rule 13 PCT since there is no technical relationship between the two above mentioned set of claims since the invention defined in the above-mentioned two sets of claims are not linked by a common general inventive concept. The fact to precise that the packaged drug is for use with a drug delivery device does not render the two sets of claim unitary.

Only the first set of claims has been examined since no further examining fees have been paid as requested by the examining Authority.

See point V of the report:

1. The present application does not meet the requirements of Article 33 (2) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33 (2) PCT. Indeed, document D1 discloses all the features of the claims, in particular the figures and the description. Even by accepting the new added feature it is considered to be a result to be achieved and should therefore have been characterized by technical features.
Moreover, no mention is made in present claim 1 to show that the force generating means and the force transmitting means are configured very differently over the delivery device of D1, as stated by the applicant in the written procedure dealing with document D1.
The same objection applies to DE-B-3525347 (D2), see in particular claims 1-4, 8 and figures 1-4.

2. A combination of the features of any of dependent claims with claim 1 would not result in an independent Claim involving an inventive step, since all the features appear to represent commonly known, non-inventive modifications.

5. The description should have been brought into conformity with the new claims to be filed; care should be taken during revision, especially of the introductory portion including any statements of problem or advantage, not to add subject-matter which extends beyond the content of the application as originally filed (Art. 34 2) b)).

6. To meet the requirements of Rules 6 3 b) the independent claim should have been properly cast in a two part form, with those features which in combination are part of the nearest prior art being placed in the first part.

7. To meet the requirements of Rule 5.1 a vi, the cited documents should have been identified in the description and the relevant background art therein is to be indicated.

8. Although claims 1, 35 and 37 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness.

Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claims makes it difficult, if not impossible, to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the protection.

Hence, claims 1, 35 and 37 do not meet the requirements of Article 6 PCT.

CLAIMS

1. A drug delivery device (10) comprising:

i) a housing (12);

ii) a means (14) for generating a force capable of pushing a drug (16) from a packaging (18) into a human or animal body;

iii) a means (20) for transmitting said force to push the drug (16) from the packaging (18) into the human or animal body; and

iv) a means (38, 42b) for triggering the device

wherein said force generating means (14) and said force transmitting means (20) are configured to push the drug (16) from the packaging (18) into the human or animal body at a velocity of less than 20m/s.

2. A drug delivery device as claimed in claim 1 wherein the housing defines:

i) an upper barrel (28), at one end of the device, which houses the force generating means (14); and

ii) a lower barrel (30), at the end remote from the upper barrel, which houses:

a) a packaged drug (100); and

b) the means (20) for transmitting said force to push the drug (16) from the packaging (18)

said lower barrel being in operative communication with said upper barrel and said packaged drug (100).

3. A drug delivery device (10) as claimed in claim 2 further comprising

v) a means (22) for receiving the packaged drug (100); and

vi) a means (24) for priming the device.

4. A drug delivery device as claimed in any of the preceding claims wherein the means (14) for generating a force capable of pushing a drug (16) from a packaging (18) into a human or animal body delivers a force of from 10 - 40N.

5. A drug delivery device as claimed in any claim 2 wherein the means (20) for transmitting said force to push the drug (16) from the packaging (18) causes the drug to be pushed from the packaging at less than 10m/s.

6. A drug delivery device as claimed in claim 3 wherein said packaged drug (100) is slidably disposed in the means (22) for receiving the packaged drug.

7. A drug delivery device as claimed in any of claims 2 to 6 wherein the packaged drug (100) is slidably disposed in the lower barrel (30) and comprises a packaging (18) containing a drug (16), said packaging comprising a housing (18a, 18b) having a channel (106; 106a, 106b) running there through in which is disposed a drive pin or other element (108), a skin piercing means (110; 112) and the drug (16);
said housing further comprising

i) a region (102) allowing the packaged drug to be slidably mounted to the drug delivery device (10) at receiving means (22); and

ii) an end (104) adapted to engage and tension the skin.

8. A drug delivery device as claimed in claim 7 wherein the skin piercing means is a pioneer projectile (110), a syringe needle (112) or the head of a drug splinter.

9. A drug delivery device as claimed in claim 7 or 8 wherein the drive pin or other element (108) has a flat or enlarged head (108a).

10. A drug delivery device as claimed in claim 7, 8 or 9 further comprising a resilient means (114) below or otherwise in association with the drive pin or other element (108) to ensure the drive pin is withdrawn after use.

11. A drug delivery device as claimed in any of the preceding claims wherein the means (14) for generating the force capable of pushing the drug (16) is a spring.

12. A drug delivery device as claimed in claim 11 wherein the spring is a coil or gas spring.

13. A drug delivery device as claimed in claims 11 or 12 wherein the force generated by the spring is adjustable.

14. A drug delivery device as claimed in claim 13 wherein a screw cap (32) and compression bar (34) provide a means for adjusting the force generated by the spring.

15. A drug delivery device as claimed in any of claims 11 - 14 further comprising a spring follower (36).

16. A drug delivery device as claimed in any of the preceding claims wherein the means (20) for transmitting the force is a striker.

17. A drug delivery device as claimed in claim 16 wherein the striker is a hammer.

18. A drug delivery device as claimed in claim 16 or 17 wherein a region (38) of the striker is shaped to fit a correspondingly shaped surface (42b) in a wall (42) separating the upper (28) and lower (30) barrels defined by the housing (12) such that the striker (20) is aligned to strike the drive pin (108) or other element in the packaged drug (100) on actuation.

19. A drug delivery device as claimed in claim 18 wherein the striker comprises a substantially frustoconical shoulder region (38) which engages a substantially frustoconical surface (42b) in the wall (42) separating the upper (28) and lower (30) barrels defined by the housing (12).

20. A drug delivery device as claimed in claim 15 wherein the means (20) for transmitting the force comprises a substantially conical end (20a) and the spring follower (36) has a correspondingly shaped recess (36a) in the underside thereof.

21. A drug delivery device as claimed in any of the preceding claims wherein the packaged drug (100) and striker (20) are slidably mounted in the device such that the device can be can be primed by pushing the device against the skin.

22. A drug delivery device as claimed in any of claims 19 – 21 wherein the device comprises a slewing spring (44), a sliding piston (48) having an aperture (46) therein and the striker (20), all housed in the lower barrel (30) and the device is triggered by the sliding of the piston (48) up the lower barrel (30) until shoulder region (38) of the striker (20) engages shaped surface (42b) and aligns the striker with the aperture (46) in the sliding piston (48) such that the striker moves down the aperture under the action of the force generating means (14).

23. A drug delivery device as claimed in any of the preceding claims wherein the device is primed and actuated by a single action.

24. A device as claimed in claim 23 wherein pushing the packaged drug (100) up the lower barrel (30) with sufficient force causes the device to be primed and actuated.

25. A device as claimed in claim 23 or 24 wherein the action of pushing the packaged drug up the lower barrel (30) with sufficient force causes the sliding piston (48) to move up the lower barrel (30) thereby causing the striker (20) to be pushed up the lower barrel (30) out of a first position in which it is not axially aligned with the aperture (46) in the sliding piston which operatively communicates with the packaged drug and at the same time acts on a spring follower (36) in the upper barrel (28) causing the spring (14) to be compressed and the device primed such that when the required delivery force is generated the striker (20) is axially aligned with the aperture (46) of the sliding piston (48) and is thus actuated such that the spring (14) acts through the spring follower (36) and striker (20) upon the drive pin (108) or a like element in the packaged drug (100) to deliver the drug (16) into the human or animal body.

26. A device as claimed in any of claims 1 – 22 wherein the device is primed and actuated by two separate actions.

27. A drug delivery device as claimed in any of claims 2 - 25 wherein the upper barrel and lower barrel are formed as separate components.

28. A drug delivery device as claimed in any of the preceding claims wherein the drug is in a contained form.

29. A drug delivery device as claimed in claim 28 wherein the drug is either:
a liquid contained by a membrane;
a liquid with a viscosity of at least 500 centipoises, more preferably at least 5000 centipoises, and more preferably still at least 100,000 centipoises;
a semi solid,
a paste,
a gel or a solid.

30. A drug delivery device as claimed in claim 1 further comprising a packaged drug as an integral part of the device.

31. A drug delivery device as claimed in any of the preceding claims in which the device and/or packaged drug is sealed in a foil pouch or the like to prevent ingress of, for example, moisture, oxygen, light, bacteria or other drug degrading or contaminating agents.

32. A drug delivery device as claimed in any of the preceding claims wherein the tip of the pioneer projectile or needle is positioned a few mm in from end (104) of the packaging (18) such that it is moving when contacting the skin.

33. A drug delivery device as claimed in any of the preceding claims wherein the end (104) about the exit of the channel (106) is in the form of a substantially annular ring located immediately about the channel (106) exit and having a depth and width in the range 1.5mm to 6 mm.

34. A drug delivery device as claimed in any of the preceding claims further comprising a positive lock retention system to ensure the packaged drug (100) does not come away from the device under gravity yet is free to slide up the device.

35. A single use drug delivery device (10) comprising:
i) a housing (12);

ii) a pre-primed means (14) for generating a force capable of pushing a drug (16) from a packaging (18) into a human or animal body;
iii) a means (20) for transmitting said force to push the drug (16) from the packaging (18) into the human or animal body;
iv) a packaged drug (100) forming an integral part of the device; and
v) a means for triggering the device
wherein said force generating means (14) and said force transmitting means (20) are configured to push the drug (16) from the packaging (18) into the human or animal body at a velocity of less than 20m/s.

36. A device as claimed in claim 35 wherein the means for triggering the device is an actuation button or like element.

37. A single use drug delivery device (10) comprising:
i) a housing (12);
ii) a means (14) for generating a force capable of pushing a drug (16) from a packaging (18) into a human or animal body;
iii) a means (20) for transmitting said force to push the drug (16) from the packaging (18) into the human or animal body;
iv) a packaged drug (100) forming an integral part of the device;
v) a means for priming (24) the device; and
vi) a means (38, 42b) for triggering the device
wherein said force generating means (14) and said force transmitting means (20) are configured to push the drug (16) from the packaging (18) into the human or animal body at a velocity of less than 20m/s.

38. A packaged drug (100), for use with a drug delivery device, comprising a packaging (18) containing a drug (16), said packaging (18) comprising a housing (18a, 18b) having a channel (106) running there through and in which is disposed a drive pin or other element (108), a skin piercing means (110; 112), and the drug (16), said housing (18a, 18b) further comprising

i) a region (102) allowing the packaged drug (100) to be slidably mounted to the drug delivery device (10); and

ii) an end (104) adapted to engage and tension the skin.

39. A packaged drug as claimed in claim 38 wherein the skin piercing means is a pioneer projectile (110), syringe needle (112) or the head of a drug splinter.

40. A packaged drug as claimed in claim 38 or 39 wherein the drug is in the form of a drug splinter.

41. A packaged drug as claimed in any of claims 38 to 40 wherein the housing is adapted to ensure the packaged drug positively locks to the device yet is free to slide therein.

42. A packaged drug (100) as claimed in any of claims 38 – 41 wherein the packaging (18) is substantially T- shaped.

43. A packaged drug as claimed in any of claims 38 – 42 wherein the drive pin has a flat and/or an enlarged head (108a).

44. A packaged drug as claimed in any of claims 38 – 43 further comprising a resilient means (114) below the drive pin head to ensure the drive pin is withdrawn after use.

45. A packaged drug as claimed in any of claims 38– 42 in which the packaging comprises a two-part housing (18a, 18b).

46. A packaged drug as claimed in any of claims 38 to 42 comprising a pioneer projectile.

47. A packaged drug as claimed in any of claims 38 to 46 wherein the drug is held in a contained state.

48. A packaged drug as claimed in any of claims 38 to 47 wherein a hollow injection needle (112) is disposed in the channel (106) towards end (104) and a contained liquid drug (16) is disposed in the channel (106) there above.

49. A packaged drug as claimed in claim 48 wherein the contained liquid drug comprises a receptacle (120) slidably disposed in the channel and having a puncturable base (122), a top (124) sealable with the drive pin or element (108) for pushing

i) the receptacle against the needle, and

ii) the needle into the human or animal body

thereby causing the release of the drug (16) out of the channel and into the human or animal body when it is acted upon by the device (10)

50. A packaged drug as claimed in claim 48 further comprising a resilient spacer (126) between the needle and the receptacle.

51. A packaged drug as claimed in any of claims 48 to 50 further comprising a resilient means (114) associated with the needle such that the needle is automatically withdrawn after use.

52. A packaged drug as claimed in any of claims 48 to 51 in which the needle is sharp at both of its ends.

53. A packaged drug as claimed in claim 38 comprising a receptacle (120) housing the drug (16) said receptacle having a breakable base (122) and being sealed by the drive pin (108) or other element which drive pin or other element comprises an elongate body (127) and a plurality of flexible arms (128).

54. A packaged drug as claimed in claim 53 in which the arms (128) of said element (108), in use, ride over one or more ramped surfaces (130) provided on the housing such that they are displaced and / or break away from the elongate body (127) so the elongate body of the drive pin can travel down the receptacle (120), causing the drug (16) to be expelled from the base(122) of the receptacle which breaks under the pressure exerted thereon.

55. A packaged drug as claimed in claim 53 or 54 further comprising a pioneer projectile (110) below the base of the receptacle.

56. A packaged drug as claimed in claim any of claims 38-55 wherein a placebo is disposed behind the drug (16).

57. A method of delivering a drug to a human or animal body through the skin comprising administering a drug using a device as claimed in any of claims 1 to 37 or a packaged drug as claimed in any of claims 38 to 56.